REMARKS

Claims 10-18 have been added. Accordingly, upon entry of the above amendment, claims 1-18 will be pending and under consideration in the application.

Double Patenting Rejection

Claims 1-9 stand provisionally rejected on grounds of nonstatutory obviousness-type double patented based on claims 1-10 of copending application number 10/572,226.

Enclosed herewith is a terminal disclaimer to overcome the double patenting rejection.

Rejection Under 35 U.S.C. § 103

Claims 1-9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,037,333 (hereinafter referred to as "Panjwani") in view of U.S. Patent Application Publication No. 2003/0149090 (hereinafter referred to as "Gehlsen et al.").

The Examiner alleges that the claims "are drawn to methods of treating urinary tract infections (UTI) with n-acetyl glucosamine (NAG)." This is substantially correct.

Panjwani is relied upon for teaching methods of inhibiting microbes with compositions comprising NAG.

Gehlsen et al. is relied upon for teaching treatment of microbial infections, including UTIs with "the same drugs."

The purported rationale for the rejection is that it would have been obvious to the person of ordinary skill in the art at the time the invention was made "to treat the various microbial infections of '090 [Gehlsen et al.], including UTI's with NAG drugs of '333 [Panjwani]." The alleged "logic flows from the fact that '333 [Panjwani] teaches NAG is effective in treating microbe infections broadly, and '090 [Gehlsen et al.] teaches to treat microbial infections, including UTI's with the same class of compounds."

It is further alleged that the person of ordinary skill in the art would have had a reasonable expectation of successfully treating UTIs with NAG because "UTI's are known to be caused by microbes and '090 [Gehlsen et al.] teaches their compositions can be effective in treating microbes of the gastrointestinal, muscle, eye, genitourinary tract, respiratory,

blood, liver, kidney, etc."

Thus, it is the Examiner's position that Panjwani broadly teaches the treatment of microbial infections with NAG, that Gehlsen et al. teaches that "the same class of compounds" can be used for treating UTIs, and that the person of ordinary skill in the art would therefore expect that NAG can be effectively administered for treating all microbially induced diseases, including UTIs.

While Panjwani indicates that the invention relates to compositions for inhibiting microbes, this cannot be reasonably interpreted as a broad teaching that NAG can be administered to effectively treat all microbially induced diseases. This statement by Panjwani is merely a statement concerning the field to which the invention pertains, and is not a statement regarding the breadth of the invention. Rather than broadly teaching that NAG is effective for treating all microbial infections, Panjwani expressly states that the method of the invention is used for treating diseases caused by parasitic microorganisms selected from Acanthamoeba and Pseudomonas and more preferably microorganisms that secrete proteinase as part of the pathogenic mechanism of the organism (see col. 1, lines 35-49). Thus, rather than teaching that NAG is effective for treating generally any type of microbially infection, Panjwani is expressly teaching that NAG is effective for treating Acanthamoeba infections of the skin, brain or eye, and Pseudomonas infections of the eye or lungs. It is further disclosed by Panjwani that the methods of the invention are used "for inhibiting microbial proteinase secretion" (see col. 2, lines 8-9). The method involves co-administration or contemporary administration of NAG and methyl-α-mannopyranoside (see col. 2, lines 9-15). Panjwani's invention is based on the discoveries that administration of NAG inhibits Acanthamoeba-induced host cell damage, and reduces secretion of cytotoxic proteinases by Acanthamoeba; and that methyl-α-mannopyranoside inhibits adhesion of Acanthamoeba to corneal surface cells (see col. 2, lines 34-43).

All of the specific examples in the Panjwani patent are directed to the treatment of Acanthamoeba-induced cyctotoxicity.

Upon perusal of the Panjwani patent, the person of ordinary skill in the art would understand that the disclosed treatment is very specifically directed to the treatment of disease induced by Acanthamoeba infection, and that the author has speculated that the

method may also be effective for treating disease induced by Pseudomonas. Panjwani also speculates that the invention may have broader application in the treatment of other diseases caused by microorganisms that secrete proteinase as part of their pathogenic mechanism.

Panjwani does not teach, suggest, or provide any reason to cause the person of ordinary skill in the art to suspect that NAG can be administered as a treatment for all diseases caused by any type of microbial infection. Thus, the foundation of the rejection is clearly erroneous, rendering the rejection defective, such that withdrawal of the rejection is proper.

Gehlsen et al. disclose that enzymatically produced reactive oxygen metabolite-mediated oxidative (ROMs) damage can be caused by various bacterial, fungal and protozoal infections, and that such damage, including damage to the genitourinary tract, can be inhibited or reduced by administration of a compound that inhibits reactive oxygen metabolite (ROM) production or scavenges ROMs. Disclosed ROM scavengers include the enzymes catalase, superoxide dismutase (SOD), glutathione peroxidase, ascorbate peroxidase; the vitamins A, E and C; and the minerals selenium and manganese (see paragraph 22). Disclosed ROM production inhibiting compounds include histamine and histamine-derived compounds; NADPH oxidase inhibitors like diphenyleneiodonium; and compounds that induce the release of endogenous histamine such as retinoic acid (see paragraph 20).

NAG is not an enzyme, a vitamin, or a mineral that scavenges ROMs. Further, NAG is not an NADPH oxidase inhibitor, a histamine or histamine derivative, or a compound (such as retinoic acid) that induces the release of endogenous histamine. Thus, Gehlsen et al. do not teach the treatment of microbial infections with the same class of drugs used by either Applicant or Panjwani. Therefore, Gehlsen et al. does not teach what it is relied upon for in the rejection. Accordingly, the rejection is clearly defective, such that withdrawal of the rejection is proper.

The two applied references teach the treatment of different diseases, caused by different classes of infectious microorganisms that employ different pathogenic mechanisms, and that are treated using different classes of drugs.

There is not any reasonable relationship between the treatment of disease induced by proteinase secretion using NAG administration, and the treatment of ROM-mediated disease using unrelated compounds, such as enzymes, vitamins, minerals, NADPH oxidase inhibitors, histamine and/or histamine derivatives, that would lead the person of ordinary skill in the art to combine the referenced teachings. It is not logical to expect that NAG would be effective for treating UTIs based on the disclosed effectiveness of unrelated compounds in the treatment of UTIs, and/or based on the disclosure of the effectiveness of NAG administration for treating different diseases induced by a different pathogenic mechanism.

Panjwani does not disclose treatment of UTIs, and Gehlsen et al. do not disclose the use of NAG. There is an enormous gap between the disclosure of Panjwani and that of Gehlsen et al. which would prevent the person of ordinary skill in the art from combining the teachings of the applied references. A person of ordinary skill in the art could not reasonably conclude that because NAG is effective for treating disease caused by proteinase secretion, and ROM inhibiting/scavenging compounds are effective for treating ROM-mediated diseases, NAG would also be effective for treating a particular ROM-mediated disease.

In view of the numerous and clear deficiencies in the rejection, it is respectfully submitted that a withdraw of the rejection based on the teachings of Panjwani in view of Gehlsen et al. is appropriate and necessary.

New Claims

Claims 10-18 have been added to more narrowly define inventions disclosed in the original patent specification. Specifically, new claims 10-18 require a method in which N-acetyl-D-glucosamine is the only active ingredient in the medicament used for treating urogenital tract infection. Support for the amendment can be found, for example, in paragraph 5 of the specification, which expressly states that Applicant surprisingly discovered that "N-acetyl-D-glucosamine could be used as the only active ingredient as a medicament for healing urogenital tract infection."

CONCLUSION

In view of the above amendments and remarks, it is submitted that the application is in condition for allowance and notice of the same is solicited.

Respectfully submitted,

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Date

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